

**Notice of Allowability**

Application No.

10/790,768

Applicant(s)

KARAS, MICHAEL

Examiner

Anand U. Desai, Ph.D.

Art Unit

1653

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to May 24, 2006.
2. ☒ The allowed claim(s) is/are 1-3, 7-9, 13 and 29-36.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 20060524
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### DETAILED ACTION

1. This office action is in response to Amendment filed on May 24, 2006. Claims 4-6, 10-12, and 14-28 have been cancelled. New claims 31, and 32 have been added. Claims 1-3, 7-9, 13, and 29-32 are currently pending and are under examination.

### Withdrawal of Rejections

2. The rejection of claims 7-9, and 13 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as being indefinite is withdrawn.
3. The rejection of claims 1-3, 7-9, 13, 29, and 30 under 35 U.S.C., 1<sup>st</sup> paragraph, scope of enablement is withdrawn.
4. The rejection of claims 1-3, 7-9, 13, 29, and 30 under 35 U.S.C., 1<sup>st</sup> paragraph, written description is withdrawn.

### EXAMINER'S AMENDMENT

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Joseph M. Skerpon on August 9, 2006.

Examiner's amendment to the claims:

7. (Currently Amended) A complex comprising a cargo moiety complexed with a polypeptide comprising with a protein transduction domain (PTD)-linked to a cargo moiety wherein said polypeptide is capable of complexing with said cargo moiety and wherein the PTD

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comprises Arg-Lys-Met-Leu-Lys-Ser-Thr-Arg-Arg-Gln-Arg-Arg (SEQ ID NO:1), and wherein the complex can traverse a cellular membrane.

13. (Currently Amended) The complex of claim 7 wherein ~~the complex~~ said polypeptide comprising said PTD is a fusion protein.

33. (New) A conjugate comprising a polypeptide with a protein transduction domain (PTD) linked to a cargo moiety, wherein the PTD comprises Arg-Lys-Met-Leu-Lys-Ser-Thr-Arg-Arg-Gln-Arg-Arg (SEQ ID NO:1), and wherein the conjugate can traverse a cellular membrane.

34. (New) The conjugate of claim 33, wherein the cargo moiety is selected from the group consisting of a small molecule, a nucleic acid, and a polypeptide.

35. (New) The conjugate of claim 33, wherein the conjugate comprises a fusion protein.

36. (New) The conjugate of claim 33, wherein the cargo moiety is  $\beta$ -galactosidase or alkaline phosphatase.

***Allowable Subject Matter***

6. Claims 1-3, 7-9, 13, and 29-36 are allowable.

7. The following is an examiner's statement of reasons for allowance: The prior art does not disclose a protein transduction domain comprising SEQ ID NO: 1. Wadia and Dowdy review the art of protein transduction domain mediated cellular translocation. Wadia and Dowdy describe the wide variety of cargo that can be translocated into multiple cells. Small molecules, peptides, antisense nucleic acid, full-length proteins, nanobeads and liposomes comprising protein transduction domains have been efficiently translocated into cells (see particularly page 53, figure 1). Schwarze et al. describe the use of protein transduction domains for the

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unrestricted delivery into all cells (see entire document, particularly page 294, 1<sup>st</sup> indented paragraph, left hand column).

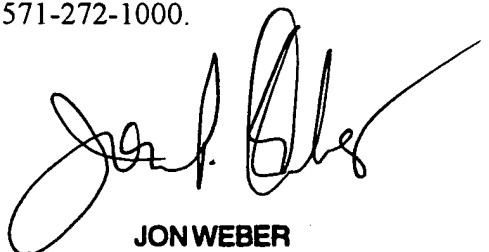
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

August 8, 2006



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**